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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,125	11/18/2003	Gerald Birk	1/1200-1-C1	6103
28501	7590	04/06/2004	EXAMINER	
BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877			CHEU, CHANGHWA J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,125	BIRK ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/3/2003</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's filed on 12/5/2003 as a continuation of case No. 09/823,150 has been received and entered into record and considered.

Currently, claims 1-5 are under examination.

Sequence Compliance Rule

Applicant is requested to change the recited polypeptides into designated SEQ ID No. (See 37 CFR 1.1821 where "Nucleotide and/or amino acid sequences as used in § § 1.821 through 1.825 are interpreted to mean an unbranched sequence of *four or more amino acids* or an unbranched sequence of *ten or more nucleotides*.")

Claim Rejections - 35 USC § 112

New Matter

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
2. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claim 1 and 5 recite a modified substrate with the sequence of Lys-Lys-Lys-Gly-Pro-Trp-Leu-Glu-Glu-Glu-Glu-Glu-Ala-Tyr-Leu-Asp-Phe. The recited sequence does not support from the parent or instant specification. Therefore, it is deemed a new matter under 35 U.S.C. 112, first paragraph.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, line 2, "PEG 2000 sensor" is vague and indefinite. It is suggested that applicants use the polyethylene glycol" for the PEG abbreviation.

With respect to claim 1, line 6, "Poly(Glu, Tyr) 4:1" is vague and indefinite. It is suggested that applicant use "poly(L-Glu, L-Tyr) sodium salt 4:1 for the claim language.

Response to Applicant's Argument

5. With respect to the terms "PEG 2000" and "Poly (Glu, Tyr) 4:1) rejections under 35 U.S.C. 112, second paragraph, applicants describe the content of each term. (See Remarks page 1-2). Applicants' arguments have been considered, and the examiner suggests that applicants use the full name to avoid vagueness and ambiguities. (See this Office Action)

6. With respect to the issue of trademark on the "RaytideTM EL", applicants amend claim language by deleting trademark and providing information on a specific sequence disclosed by Oncogen incorporation in the year of 2002. (See page 4, second paragraph) Applicants'

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argument has been considered but are not persuasive. First, the newly recited sequence is disclosed AFTER the filing date of the parent application. (3/30/2001) There is a question whether both "RaytideTM EL" materials are identical in terms of composition. The second issue is that this newly recited sequence is a new matter not supported by the specification. Accordingly, applicants do not possess this newly recited sequence when the application was filed.

Allowable Subject Matter

7. Claims 1-5 would be allowed if applicants delete the unsupported new matter from the claim 1 as discussed in this Office Action.

8. The following is an examiner's statement of reasons for allowance:

No prior art teaches or suggests using the recited method to measure a phosphorylated substrate by using Reflectometric Interference Spectroscopy by an antibody/phosphorylated receptor with a specific SEQ ID No. modified substrate as recited in this instant application. The closest prior art is taught by Birkert et al. (Analytical Biochemistry (2000) 282: 200-228) But, Birkert et al. do not teach explicitly with the specific limitation recited in this invention.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

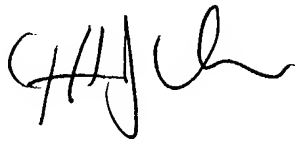
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu

Examiner

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March 23, 2004



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

04/05/04